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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,431	08/22/2007	James Samsoondar	411044.00004	7033

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,431	SAMSOONDAR, JAMES	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/30/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because: The declaration should claim foreign priority to Canadian patent application CA 2458497 under 35 USC 119(a)-(d).

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprising". In addition, the abstract from the corresponding PCT application should be placed onto a separate sheet. Correction is required. See MPEP § 608.01(b).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 3,761,408) in view of Carroll et al (US 6,706,536).

Lee teaches of a method and apparatus for separating blood constituent components in a whole blood sample. The separating apparatus comprises an outer container 13 having an open first end 15 and a closed second end 17. The container 13 can be a conventional cylindrical vacuum tube. A penetrable elastomeric closure or stopper 19 seals the open end 15 of the container 13. The stopper 19 has a membrane 30 therein that is made from a rubber or other thin sheet material so that the membrane can be pierced with a needle. In using the device, Lee teaches that the container 13 is evacuated. A cannula or needle penetrates the stopper 19 and delivers a sample of whole blood 35 into the container, wherein the blood is drawn into the container by the vacuum within the container 13. After a sufficient amount of blood has been collected in the container 13, the container 13 is placed into a centrifuge 41, illustrated schematically and in phantom in Figure 3 of Lee. The container 13 is inserted into the centrifuge 41 upside down with the stopper portion resting in a support portion or pocket 43 of the centrifuge 41. The outer periphery of the stopper 19 is curved to conform to the shape of the centrifuge pocket 43 which in the past had received the container bottom 17 instead of the

container first end 15. The pocket 43 is caused to spin rapidly about a central axis 45 of the centrifuge 41, thereby forcing the larger blood cells suspended in the plasma to move against the stopper 19. The centrifuging of the container causes the whole blood sample therein to separate out into a cell layer, a gel layer and a plasma layer, wherein the centrifuging produces in relative juxtaposition the stopper 19, the first end of the container 15, the cell layer 37, the gel layer, the plasma layer 39 and the second end of the container 17. Lee teaches that the centrifuging is maintained at approximately 3,000 r.p.m. for about 10 minutes to obtain maximum desired constituent separation. Once the centrifuging is completed, the container is upended and the cell/gel layer 37 is withdrawn from the container. The plasma 39 is left in the container 13 at the second end 17. Lee teaches that the container 13 may then be used for subsequent chemical analysis of the plasma 39. Lee teaches that the apparatus and method for separating blood cells from the plasma portion of a whole blood sample is advantageous since it avoids having to use a pipette to transfer the separated plasma from the centrifuge tube to a second container for subsequent chemical analysis, and avoids having to use two containers for the analysis of each blood sample. A technician does not have to manually transfer the plasma portion of the separated blood sample from one container to another, thus avoiding the potentially harmful blood sample from coming into contact with the technician and the surrounding environment. See lines 57-72 in column 1, lines 1-15 in column 2, lines 15-75 in column 3, lines 20-75 in column 4 and lines 1-14 in column 5, and figures 1-4 in Lee. Lee fails to teach that the subsequent chemical analysis of the separated plasma portion 39 held within the tube 13 involves inserting the second end 17 of the tube 13 holding the plasma portion 39 into a spectrophotometric device.

Carroll et al teach of a method and apparatus for spectrophotometrically analyzing a blood sample that has been separated into a cell portion and a plasma portion by centrifugation. The method comprises collecting a whole blood sample into a sample container 8. The sample container 8 is constructed with a walled body portion 40 with a first pair of opposing walls 41, 42, a second pair of opposing walls 43, 44, and a flat bottom 45. A cover 46 is provided at the container end opposite the bottom 45 and seals the entrance to the container space 47. The container 8 is formed from optically transparent plastic or glass. A negative pressure is applied to the container space 47, relative to the atmosphere, so that a vacuum is present in the space 47. The vacuum is controlled so that it pulls a predetermined quantity of blood into the container 8. The container top 46 is made from a material which maintains the vacuum and which also can be pierced by a needle so that blood taken up through the needle can be inserted into and drawn into the container space 47. After a blood sample is drawn into the container space 47 via the vacuum in the space 47 and a needle piercing the container top 46, the container 8 is centrifuged for at least about 5 minutes to separate and isolate the plasma from the formed cellular elements of the blood, such as red blood cells, platelets and white blood cells. The container 8 depicted in Figure 1 of Carroll et al shows the separated blood comprising a first lower level 61 containing red blood cells, white blood cells and platelets, a second gel layer 62 and a third or upper layer 63 containing plasma. A chemical analysis of the separated plasma layer 63 is performed by inserting the container 8 into a spectrophotometric device between a light source 4, such as a laser, and a detection means 10, such as a photocell. The light source 4 produces a beam of light 6 which passes through the separated plasma layer 63 in the container 8 so as to spectrophotometrically analyze the plasma sample. Carroll et al teach that the

spectrophotometric analysis of the separated plasma sample is performed without having to transfer the separated plasma sample to a second container. Rather, the analysis of the separated plasma layer 63 is performed in the same container in which the whole blood sample from which the plasma originated was collected into and centrifuged. Carroll et al teach that the method and apparatus are advantageous since they allow a blood sample to be spectrophotometrically analyzed while the blood is contained within the same container into which it is originally drawn. This reduces the risk of contact with the blood by medical personnel since the separated plasma does not have to be transferred to a different container for optical analysis. See Figures 1 and 3, lines 27-67 in column 4, lines 1-32 in column 5, lines 60-67 in column 5, lines 41-67 in column 6, lines 1-8 and 61-67 in column 7, and lines 1-30 in column 8 of Carroll et al.

Based upon a combination of Lee and Carroll et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to chemically analyze the separated plasma portion 39 held within the container 13 taught by Lee by inserting the second end 17 of the container holding the plasma portion 39 into a spectrophotometric device since Carroll et al teach that a spectrophotometric chemical analysis of a plasma sample separated from a whole blood sample by centrifugation is a routine analysis in order to measure analytes within the plasma sample, and also teach that it is advantageous to spectrophotometrically analyze a separated plasma sample in the same container in which the whole blood sample from which the plasma originated is centrifuged, similar to the separated plasma sample located in the container 13 taught by Lee that remains within the container 13 during both centrifugation and subsequent chemical analysis so as to avoid having to transfer the plasma sample to a separate tube for analysis and the potential contamination of a technician during such transfer with a blood

sample. With regards to the volume of whole blood collected into the container and the conditions of centrifugation such as temperature, length of time and strength of centrifugation as recited in the instant claims, it would have been obvious to one of ordinary skill in the art to vary the volume of whole blood collected into the container taught by Lee and the conditions of centrifugation to the values recited in the instant claims since Applicant admits in the instant specification that such parameters are understood by those of skill in the art as being adjustable, and in the absence of any teaching of criticality concerning these parameters, it would have been prima facie obvious that one of ordinary skill in the art would recognize these parameters to be result effective variables whose values are a matter of routine optimization. With regards to claim 10, it would have been obvious to one of ordinary skill in the art to provide enough whole blood sample to the container taught by Lee so as to obtain a plasma layer of at least 3 mm or more when the container is vertical so as to ensure that there is a sufficient quantity of the plasma sample present in the container 13 for the subsequent chemical analysis of the plasma sample 39 taught by Lee, in particular for the spectrophotometric chemical analysis as taught by Carroll et al. With regards to claims 11-12, it would have been obvious to one of ordinary skill in the art to use any type of conventional centrifuge for separating the whole blood sample taught by Lee into a cell layer, a gel layer and a plasma layer, such as a fixed angle rotor or a swing arm rotor, since these types of conventional centrifuges are known for their ability to separate a whole blood sample into its different phases. With regards to claim 14, it would have been obvious to one of ordinary skill in the art to formulate the second end 17 of the container 13 taught by Lee with a flat bottom, similar to the flat bottom of the container 8 taught by Carroll et al, so as to facilitate

measurements of the plasma sample in the container 13 taught by Lee with the spectrophotometric device taught by Carroll et al.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Goldstein et al who teach of a cuvette used for centrifugal testing and analysis of a specimen by a spectrophotometer.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

November 18, 2008

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797